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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/622,621

07/18/2003

Jan Weber

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

04/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/622,621	Applicant(s) WEBER ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,38 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/27/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 1/18/2008 in which claims 27 and 63 were amended. Currently claims 27-38 and 63-68 are pending for examination in this application.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 recites the limitation "... respective outer and inner surfaces..." in the first and second layers. There is insufficient antecedent basis for this limitation in the claim.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 12/27/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 102

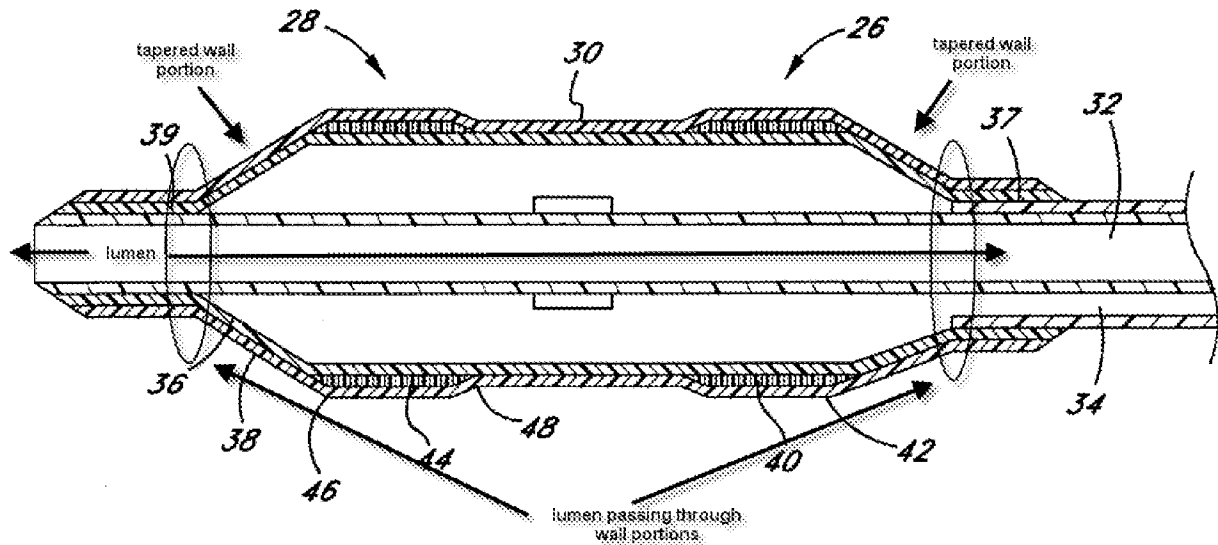
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29, 32-37 and 65-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Crocker et al. (6,120,523). Crocker et al. discloses a focalized intraluminal balloon.

Regarding claims 27-29, 32-37 and 65-68, Crocker et al. discloses a medical balloon (18) having a longitudinal axis and proximal (26) and distal (28) ends, the balloon formed of a polymer material (col 6, ln 25-40), the balloon connecting to a coaxial shaft (37) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (39), and having a central body wall portion (30) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (38, 42) portions, respectively, wherein the balloon further comprises a lumen (32) extending longitudinally therethrough, said lumen passing through the proximal and distal wall portions of the balloon (Figures 1-4).

**FIG. 2**

Crocker et al. discloses a polymeric (cross-linked polyethylene, col 7, In 35-55) balloon and is a multi-layer polymeric film (39, 36, 38, 40, 42, 44) wherein a first (36, 48) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 2-3), with a layer comprising an elastomeric band (40, 44) that is stretched during the configuration change. Examiner asserts that the radiation cured polymer is a product by process limitation in which the resultant radiation cross-linked product is indistinguishable from the heat cross-linked polyethylene of Crocker et al.

Claim Rejections - 35 USC § 102

Claims 27-29, 32-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamlin (6,132,824). Hamlin discloses a multi-layer catheter balloon.

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Regarding claims 27-29, 32-35, and 38 Hamlin discloses a medical balloon (40, 58) having a longitudinal axis and proximal (near 64) and distal (near 50) ends, the balloon formed of a polymer material (col 2, ln 30-50), the balloon connecting to a coaxial shaft (50) at a proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof (62), and having a central body wall portion (near 68) between each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall (Figures 5-6) portions, respectively, wherein the balloon further comprises a lumen (52) extending longitudinally there through, said lumen passing through the proximal and distal wall portions of the balloon (Figures 5-6). Hamlin discloses a polymeric balloon that is capable of being radiation cured and is capable of being made of a fluidizable polymer composition, that is comprised of a multi-layer polymeric film (64, 66, 68) wherein a first (64, 66) and second layers are in adherent contact over a coplanar coextensive region defining an at rest and open configuration resulting in a change of surface area (Figures 5-6).

Claim Rejections - 35 USC § 102

Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Boussignac et al. (5,000,734). Boussignac et al. discloses a probe intended to be introduced within a living body.

Regarding claims 63-64, Boussignac et al. discloses a medical balloon (1) (Figures 1-2, 4) having a longitudinal axis (along 7) and proximal and distal ends (3,4), the balloon formed of polymer material (col 3, ln 25-35), the balloon connecting to a coaxial shaft (3) at the proximal end thereof and connecting to

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the same or a different coaxial shaft at the distal end thereof, and having a central body wall (near 1) portion connected with tapering wall portions (near 5a,5b), wherein the balloon comprises a lumen (11) extending therethrough, the lumen spaced apart from the coaxial shaft (Figure 3).

Claim Rejections - 35 USC § 102

Claim 65 is rejected under 35 U.S.C. 102(b) as being anticipated by White, Jr. (4,327,734). White, Jr. discloses a therapeutic method of use for a detachable balloon assembly.

Regarding claim 65, White, Jr. discloses a balloon (20) comprising a balloon body (38) having a proximal and distal end, and the balloon comprising circumferential elastic bands (46) at the proximal end or distal end of the balloon body, the elastic bands (46) in their rest configuration have a smaller diameter than the balloon body in its rest configuration (Figure 1) verses the inflated configuration (Figures 2-3) (Figures 1-3).

Claim Rejections - 35 USC § 102

Claims 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (6,007,517). Anderson discloses a rapid exchange/perfusion angioplasty catheter.

Regarding claims 63-64, Anderson discloses a medical balloon (3) catheter (1) (Figures 1C, 2A, 3A, 10A and 11A) having a longitudinal axis (along 9) and proximal and distal ends (near 5, 6), the balloon formed of polymer material, the balloon connecting to a coaxial shaft (2) at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof,

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and having a central body wall (near 7) portion connected with tapering wall portions (near 5 and 6), wherein the balloon comprises a lumen (7) extending therethrough, the lumen spaced apart from the coaxial shaft (Figures 3A and 11A).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 30-31 are rejected under 35 U.S.C 103(a) as being unpatentable over Crocker et al. Crocker et al. meets the claim limitations as described above except for the specific embodiment being used in with a stent or with a rapid exchange catheter.

Regarding claims 30-31, Crocker et al. teaches a specific medical balloon structure that is disclosed of being used with rapid exchange and for delivery of

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stents to the vascular system (col 3, ln 40-70, col 4, ln 40-70, see summary of invention).

At the time of the invention, it would have been obvious to use the medical balloon as disclosed by the various embodiments and the disclosure of Crocker et al. in order to achieve a versatile controllable balloon element. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Crocker et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 1/18/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the references fail to show a balloon with a lumen "extending through the tapering proximal and distal wall portions (claims 27 and 63)", a balloon with multiple layers with the "first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface" (claim 32), the balloon having "elastic bands" (claim 65) and that the balloon is wherein the balloon is formed of a radiation cured polymerizable composition (claim 63).

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

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Regarding claims 27 and 63, Examiner asserts that the balloon pictured in Figure 2 meets the claim limitations as claimed. The lumen (32) of Crocker et al. passes *through* the *tapering distal and proximal wall portions* (38, 42) of the balloon. Examiner asserts that the language as claimed is insufficient to overcome the prior art of record, the broadest reasonable of the definition of "extending through" is "passing or extending from one end, side, or surface to another" *"through."* *The American Heritage® Dictionary of the English Language. 2007.* Therefore Examiner asserts that the lumen (32) of Crocker et al. indeed passes through the tapering distal and proximal portions as claimed. As suggested in the previous office action Examiner suggests further clarification of the lumen axis or opening location in order to distinguish this lumens location.

Regarding claim 32, Examiner asserts that the first (36) and second balloon (48) layers of Crocker et al. meet the claimed limitations of "having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface." Examiner asserts that the outer surface of the first layer (36) has a smaller surface area than the inner surface of the second layer (48) because of the stretched areas (near 44 and 40) which are present to accommodate the expansion limiting bands. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "Crocker et al. is silent as to these bands providing stress so as to collapse the article as disclosed in Applicants'

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specification”) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's claim is broad and does not define which layer is present in what specific location or which specific area is being functionally claimed, Examiner suggests further clarification of each of these elements.

Regarding claim 65, Examiner asserts that the bands of Crocker et al. as disclosed as “substantially non-distensible” materials (col 5, ln 20-30), therefore the materials (nylon, plyamide, polyethylene and PET) do have some elasticity and can be considered to fall under the broadest reasonable definition of an “elastic” material (easily resuming original shape after being stretched or expanded; flexible, see *elastic*. (2007). In *The American Heritage® Dictionary of the English Language*. Since the materials listed do have expansion recovery and are termed as “expansion limiting bands” they facilitate and undergo some expansion and recovery during balloon inflation and deflation states. Examiner suggest Applicant further clarify the claim with specific elastic characteristics.

Regarding claim 63, Examiner asserts that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Also

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when the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983). Therefore the balloons of Anderson (3) and Boussignac et al. (5) are composed of several different materials of which polyethylene is disclosed, Examiner considers the radiation curing of polyethylene to result in an indistinguishable product from a polyethylene product formed via a different means of curing (such as heat). If Applicant wishes to gain patentability of this process Applicant must direct method/process claims towards this specific claim scope.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 4/07/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763